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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Francesco PAOLINI et al.	Group Art Unit: 3761
Application No.: 10/500,324	Examiner: Philip R. Wiest
Filed: June 28, 2004	Confirmation No.: 8942
For: CONTROL EQUIPMENT AND METHOD FOR AN EXTRACORPOREAL BLOOD CIRCUIT	

Mail Stop Appeal Brief--Patent
Commissioner for Patents
P.O. Box 1450
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Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed August 1, 2007, and further to Board Rule 41.37, Appellants present this Appeal Brief and enclose herewith the fee of $510.00 required under 37 C.F.R. § 1.17(c). The period for filing the Appeal Brief having been extended through December 11, 2007, by a Request for a One-Month Extension of Time a fee payment filed concurrently herewith, a Notice of Panel Decision from Pre-Appeal Brief Review, indicating that this application remains under appeal, having been mailed by the PTO on October 11, 2007.

This Appeal responds to the Final Office Action mailed April 2, 2007 and the Advisory Action mailed July 6, 2007, which finally rejected claims 26 and 28-50.

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I. Real Party in Interest

Gambro Lundia AB is the assignee of record, as evidenced by the assignment recorded in this application on October 14, 2004, at Reel 015884, Frame 0042, and is the real party in interest in this appeal.

II. Related Appeals and Interferences

Appellants, Appellants' undersigned legal representative, and the assignee know of no appeals, interferences, or proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 26 and 28-50 are currently pending in this Application. In the Final Office Action mailed on April 2, 2007, the Examiner rejected claims 26 and 28-50 under 35 U.S.C. § 103(a). The final rejection of claims 26 and 28-50 is being appealed and a list of the claims on appeal is found in the attached Claims Appendix. Furthermore, each claim of this patent application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. § 282.

IV. Status of Amendments

All claim amendments have been entered.

V. Summary of Claimed Subject Matter

The claimed invention relates to control equipment for an extracorporeal blood circuit. (Specification at page 1, line 5.) The extracorporeal circuit is generally connected to the patient by means of an access needle and a return needle, or other access devices, which are inserted into a fistula formed in the patient's cardiovascular system, and are used, respectively, to collect the blood to be treated via an access branch, and to return the treated blood to the patient's cardiovascular system via a return branch. (Specification at page 1, lines 9-12.) During its travel along the extracorporeal circuit, the blood undergoes temperature variations due to the heat exchange with the surrounding environment and with the treatment fluids, when the blood purification process makes use of a treatment fluid. (Specification at page 2, lines 17-20.) It should be noted that these temperature changes are occurring during dialysis treatment, *i.e.*, during a moment when blood, and consequently, the patient, are undergoing a very stressful treatment in which toxins and a significant amount of water are removed from the blood in a relatively short period of time. (*See, e.g.*, Specification at page 1, lines 28-30.) While dialysis treatment is beneficial for the patient's survival, the treatment is perceived as a shock due to its intense action on the blood. (*See, e.g.*, Specification at page 2, lines 3-4.)

In this situation, to avoid further stress on the part of the patient who is being dialyzed it is desirable to stabilize at a certain value, the temperature of the blood returning to the patient. Ideally this stabilization should be done in the simple and gentle way in order to be carefully treat the patient's blood. (*See, e.g.*, Specification at page 2, lines 20-26.)

In general, it is exceedingly difficult to implement in a dialysis machine a method capable of precisely determining the thermal equilibrium of the blood and of compensating the temperature variations to which the patient is subject. (Specification at page 3, lines 1-3.) This is because, in order to implement such a method, it would be necessary to determine, with accuracy, all factors causing heat exchanges occurring in the blood. This, in turn, would require determining the blood temperature in a precise way by means of temperature sensors of the non-invasive type, whose accuracy is sometimes relatively low, to determine in a precise way the rate of flow of blood in the extracorporeal circuit, to determine the temperature and rate of flow of the dialysate and/or of the replacement liquid (when the blood purification process makes use of a treatment fluid), to determine various heat exchange coefficients, and also to somehow take into account the reaction of the patient as blood goes back and forth, to and from the patient, wherein the patient's reactions may affect blood temperature.. In practice, the thermal equilibrium of the blood and the control of the temperature of blood returning to the patient in the extracorporeal circuit can be established in the laboratory by using highly sophisticated instruments, but is difficult to achieve in blood purification machines. (Specification at page 3, lines 3-11.)

This invention provides control equipment for an extracorporeal blood circuit that overcomes the drawbacks of the known control equipment and which, in particular, is both efficient and easily implemented in all blood purification machines. (Specification at page 4, lines 6-8.) The control equipment is connected to a blood purification machine, in which the extracorporeal circuit comprises an access branch and a return branch connected to at least one blood treatment element; the equipment comprising a

sensor for measuring a first temperature of the blood leaving a patient along the access branch upstream of the said blood treatment element, a control unit for regulating the blood temperature as a function of the first temperature and of a reference temperature; the equipment having a device for regulating the blood temperature, connected to a portion of the return branch and downstream of the blood treatment element. (Specification at page 4, lines 9-17.)

The control equipment makes it possible to dispense with the control of the temperature of the dialysate and/or replacement liquid. By suitably locating the regulation device within the return branch, it is possible to avoid the occurrence of phenomena which might further modify the blood temperature before the treated blood is returned to the patient. Furthermore, the control equipment interacts with the return branch and with the access branch only, and can be fitted to any blood purification machine. (Specification at page 4, lines 18-23.)

Independent claim 26 is directed to an apparatus for control of an extracorporeal blood circuit connected to a blood purification machine. (Specification at page 4, lines 9-10.) The extracorporeal blood circuit includes an access branch having one end connected to at least one blood treatment element inlet and another end connected to a patient. The extracorporeal blood circuit also includes a return branch having one end connected to an outlet of the at least one blood treatment element and another end connected to a patient. (Specification at page 4, lines 10-12.) The apparatus for controlling the extracorporeal blood circuit comprises a sensor located in the access branch upstream of all blood treatment elements for measuring a first temperature of blood leaving a patient along the access branch upstream of the at least one blood

treatment element. (Specification at page 4, lines 12-13.) The apparatus further comprises a temperature regulating device for regulating the blood temperature in the extracorporeal blood circuit. (Specification at page 4, lines 13-15.) The temperature regulating device comprises a line conveying a fluid, wherein the line is coupled to a portion of the return branch downstream of all blood treatment elements to form a heat exchanger directly before the blood is returned to the patient. (Specification at page 6, lines 3-5.) The apparatus also includes a control unit connected to the temperature regulating device for controlling the blood temperature by controlling the temperature of the fluid conveyed in the line as a function of the first temperature and of a reference temperature. (Specification at page 6, lines 12-20.)

Independent claim 38 is directed to a method for controlling the circulation of blood through an extracorporeal blood circuit in a blood purification machine. (Specification at page 4, lines 25-26.) The extracorporeal blood circuit used to carry out this method comprises an access branch and a return branch. Both the access branch and the return branch are connected to at least one blood treatment element. (Specification at page 4, lines 26-27.) The method for controlling blood circulation comprises the steps of connecting the access branch to a patient and to an inlet of the blood treatment element and connecting the return branch to the patient and to an outlet of the blood treatment element. The method also includes the step of measuring a first temperature of the blood in correspondence of said access branch upstream of all blood treatment elements in the extracorporeal blood circuit. (Specification at page 4, lines 28-29.) The method further includes the step of regulating a blood temperature in the extracorporeal blood circuit as a function of the first temperature and of a reference

temperature. (Specification at page 4, lines 30-31.) The blood temperature in the extracorporeal blood circuit is regulated along a portion of the return branch and downstream of all blood treatment elements, directly before the blood is returned to the patient. (Specification at page 5, lines 1-2.)

By taking into account the temperature measured in the access branch upstream all treatment elements, it is possible to take into account the patient's reaction. Any patient receiving blood at a temperature different from body temperature may react causing the body to try to compensate. The degree of the body's compensation depends upon many factors and by simply measuring the blood temperature as blood enters the extracorporeal circuit (*i.e.*, before it interacts with other items, which may cause heat exchange to occur), the present invention provides a way of taking into account the patient's is contribution to the thermal equilibrium. (*See, e.g.*, page 2, lines 15-30.)

VI. Grounds of Rejection to be Reviewed

Claims 26 and 28-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,561,997 to Weitzel et al. ("Weitzel") in view of U.S. Patent No. 4,894,164 to Polaschegg ("Polaschegg"), and further in view of U.S. Patent No. 6,582,387 to Derek et al. ("Derek").

VII. Argument

A. Claims 26 And 28-50 Are Patentable Under 35 U.S.C. § 103(A) Over Weitzel In View of Polaschegg, And Further In View of Derek

Claims 26 and 28-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Weitzel in view of Polaschegg, and further in view of Derek. Appellants respectfully submit that the Examiner has not established a *prima facie* case of obviousness; therefore, this rejection is legally improper and should be reversed.

1. Legal Standard

In making a rejection under 35 U.S.C. § 103, the Examiner has the initial burden to establish a *prima facie* case of obviousness. M.P.E.P. § 2143. The rational to support a conclusion that a claim would have been obvious is that all of the claimed elements were known in the prior art and one skilled in the art could have combined the claimed elements by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. MPEP § 2143 (A). *See also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 U.S.P.Q.2d 1385, 1395 (2007)

To further meet this burden, the Examiner must point to some objective teaching in the prior art, coupled with the knowledge generally available to one of ordinary skill in the art at the time of the invention, that would have motivated one of ordinary skill to modify the reference or to combine references' teachings with a reasonable expectation of success in obtaining the presently claimed invention. *See* M.P.E.P. §§ 2143.01 and 2143.02; *In re Fine,* 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "Both the suggestion and the reasonable expectation of success must be found in the prior art reference, not in the applicant's disclosure." *See In re Vaeck*, 20 U.S.P.Q.2d

1438, 1442 (Fed. Cir. 1991) (*citing In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988)) (emphasis added). The Federal Circuit has stated that:

> [t]he factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record . . . Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.

See In re Lee, 277 F.3d 1338, 1344, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002) (emphasis added).

As explained by the Federal Circuit, "[o]ur case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). Therefore, this evidence must be explicitly set forth by the Examiner. *See In re Lee*, 61 U.S.P.Q.2d at 1433, 277 F.3d at 1343. *See also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, __, 82 U.S.P.Q.2d 1385, 1395-97 (2007).

2. The Examiner Has Not Met His Burden Of Establishing a Prima Facie Case of Obviousness Based on the Combination of Weitzel, Polaschegg, and Derek

a) Independent Claim 26

Independent claim 26 is not rendered obvious at least because Weitzel, Polaschegg, and Derek fail to disclose or suggest all of the elements of the apparatus for controlling an extracorporeal blood circuit recited in independent claim 26. Independent claim 26 recites, among other things, "a sensor located in the access branch upstream of all blood treatment elements for measuring a first temperature of

blood leaving a patient along the access branch upstream of said at least one blood treatment element," a "temperature regulating device comprising a line conveying a fluid, said line being coupled to a portion of the return branch downstream of all blood treatment elements to form a heat exchanger directly before blood is returned to the patient," and a "a control unit connected to said temperature regulating device for controlling the blood temperature by controlling the temperature of the fluid conveyed in said line as a function of said first temperature and of a reference temperature."

1) Weitzel

Weitzel discloses "extracorporeal circuits for receiving a body fluid from a patient; treating or processing body fluid; and returning the body fluid to the patient." (Col. 3, lines 50-53.) The Examiner contends that Weitzel discloses an apparatus having "a sensor/control unit that is capable of . . . precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit' (Column 3, lines 57-59) . . . and regulating devices (8 and 34) which are connected to the return branch downstream from the blood treatment device . . [and that] heat exchanger 8 that is connected to the circuit in order to control flow temperature, and a line 16 for conveying fluid." (September 27, 2006 Office Action at 3.) The Examiner correctly concedes that Weitzel "does not disclose that the temperature sensor is located in the access branch, upstream of all blood treatment devices, nor does it disclose that the temperature regulating device 8 is located downstream of all blood treatment elements to form a heat exchanger directly before blood reenters the patient" (April 2, 2007 Office Action at 4), both of which are elements recited in independent claim 26.

The Examiner further contends, however, that Weitzel discloses "that the control unit regulates the blood temperature . . . as a function of the blood temperature and the temperature of the body . . . and that the blood temperature is regulated as a function of the difference between the blood temperature and the reference temperature" (September 27, 2006 Office Action at 5) and "that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19), thus function according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature)." (April 2, 2007 Office Action at 3-4). Appellants disagree with the Examiner's contentions in both Office Actions. The portion of Weitzel cited by the Examiner to support these contentions is insufficient to support the Examiner's contentions. Appellants submit that Weitzel does not actually disclose that blood temperature is regulated as a function of the difference between the measured blood temperature and a reference temperature. Weitzel merely discloses that "[t]he heat exchanger 8 functions to keep blood at a physiological temperature such that any metabolic functions that the treatment device 20 carries out can be accomplished" (col. 6, lines 16-19) and that "the ability to precisely control temperature . . . [is] indicative of some other embodiments of the invention that are contemplated." (Col. 12, lines 56-64.) This passage of Weitzel merely describes the function of a known heat exchanger, which detects the actual temperature of a fluid going through the heat exchanger. The temperature of the fluid in the heat exchanger in Weitzel is then maintained within a predetermined range based on a reference temperature and irrespective of the blood temperature in the arterial branch as it is drawn from the patient. This means that according to Weitzel, if the reference temperature is 37° C,

then the blood would be kept at 37° C, irrespective of the blood temperature in the patient which, could be much different from the reference temperature. By re-introducing liquid into the patient at a temperature potentially different (reference temperature) from the temperature of the blood as it exited the patient, could undesirably add further stress on the patient.

On page 10 of the Office Action dated April 2, 2007, the Examiner opines that "the physiological temperature [disclosed in Weitzel] is equivalent to the reference temperature disclosed by Applicant [in the present invention], as it is the temperature that the heat exchanger tries to achieve." The Examiner further contends that "[i]t is inherent that the heat exchanger is regulated as a function of the difference between the blood temperature and the reference temperature because heating will occur if the temperature of the blood is lower than the reference temperature (because there is a difference between the blood and references temperatures, blood will have to be heated until the temperatures are equal." (April 2, 2007 Office Action at 10.) Appellants further disagree and submit that the Examiner's contention is misplaced. In fact, the Examiner even fails to recognize that his inherency argument the temperature regulation recited in claim 26. The Examiner contends that the blood must be heated to reach the physiological temperature

Accordingly, nowhere does Weitzel disclose or suggest that the actual temperature of the blood, measured when it exits the patient, is used in conjunction with a reference temperature of the blood to control the temperature of the blood in a different portion of the circuit (at a location immediately upstream from the point at which the blood reenters the patient), as recited in independent claim 26. Thus, despite

the Examiner's contention, Weitzel fails to disclose a "temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] **and** of a reference temperature" (emphasis added), as recited in independent claim 26.

2) Polaschegg

Polaschegg discloses an apparatus "for treating blood in an extracorporeal circuit for hemodialysis or hemofiltration fluid." (Col. 3, lines 5-7.) Polaschegg further discloses a method "for withdrawing heart from blood in an extracorporeal circuit wherein blood is brought into contact along a membrane with a treatment solution which has been heated to a temperature in a source making the treatment of fluid available such that the energy balance of the patient is maintained, the temperature of the source being controlled in that the temperature of the blood emerging from the patient is measured." (Col. 3, lines 7-15.) The Examiner contends that "Polaschegg discloses a blood treatment apparatus comprising a temperature sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1)." (April 2, 2007 Office Action at 9.) Polaschegg, however, does not disclose a "temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] **and** of a reference temperature" (emphasis added), as recited in claim 26, and thus, fails to cure the above-mentioned deficiencies of Weitzel. Thus, the detection made by the temperature sensor in Polaschegg would be of no use in the control apparatus and methods described in the present invention.

3) Derek

Derek discloses a system utilizing "an oxygenation device to generate a gas-enriched physiologic fluid and to combine it with a bodily fluid to create a gas-enriched bodily fluid." (Abstract.) The Examiner also contends that "Derek et al. discloses a blood treatment apparatus wherein a heat exchanger may be placed within the return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2)." Appellants point out, however, that the cited passage in Derek is unclear and Derek fails to provide details about the components present on return tube 50 or the structure of the tube itself. Thus, Derek does not disclose a temperature regulating device located downstream of all blood circuit elements and immediately before the blood is returned to the patient, as recited in independent claim 26. Nevertheless, Derek fails to disclose or suggest a "temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] and of a reference temperature" (emphasis added), as recited in independent claim 26. Derek is completely silent regarding the control of the blood temperature at a location downstream of all blood circuit elements and does not disclose controlling the temperature of this blood as a function of the temperature of blood measured immediately upon exiting a patient and a reference temperature. Thus, Derek fails to cure the above-mentioned deficiencies of Weitzel.

Therefore, for at least the reasons discussed above, independent claim 26 is allowable over the cited references. Accordingly, Appellants respectfully request the

reversal of the rejection of independent claim 26 under 35 U.S.C. § 103(a) as being unpatentable over Weitzel in view of Polaschegg, and further in view of Derek.

b) Independent Claim 38

For at least the reasons discussed above with respect to independent claim 26, the cited references also fail to disclose or suggest each and every limitation of independent claim 38. More specifically, the cited references do not disclose or suggest the step of "regulating a blood temperature in the extracorporeal blood circuit as a function of the first temperature [measured upstream of all blood treatment elements] **and** of a reference temperature, the blood temperature in the extracorporeal blood circuit being regulated along a portion of the return branch and downstream of all blood treatment elements, directly before blood is returned to the patient." (Emphasis added.)

Thus, independent claim 38 is allowable because neither the cited references, nor the prior art in general, disclose or suggest every limitation of independent claim 38. Accordingly, Appellants respectfully request the reversal of the rejection of independent claim 38 under 35 U.S.C. § 103(a) as being unpatentable over Weitzel in view of Polaschegg, and further in view of Derek.

c) Dependent Claims 28-37 and 39-50

Appellants submit that dependent claims 28-37 and 39-50 also are patentable under 35 U.S.C. § 103(a) over Weitzel in view of Polaschegg, and further in view of Derek at least due to the direct or indirect dependency of claims 28-37 and 39-50 from either independent claim 26 or 38 and due to their additional recitations of novel subject matter.

Thus, for at least the foregoing reasons, the 35 U.S.C. § 103(a) rejection of the dependent claims over Weitzel in view of Polaschegg, and further in view of Derek is improper and Appellants request its reversal.

1) Dependent Claim 45

Appellants further submit that dependent claim 45 is allowable over Weitzel in view of Polaschegg, and further in view of Derek, for at least the following additional reason. None of the cited references discloses or suggests "the fluid temperature being regulated as a function of the first temperature and of the reference temperature, and the fluid temperature being kept equal to the reference temperature when the pump is not in operation" (emphasis added), as recited in dependent claim 45. In the Office Action dated April 2, 2007, regarding claims 44-46, the Examiner contends that "[w]hen the pump is not turned on, fluid in the heat exchanger will remain at a temperature equal to the reference temperature." Appellants disagree. Weitzel neither explicitly, nor implicitly, discloses or suggests that fluid temperature is kept equal to the reference temperature when the blood pump is not operating. Moreover, the Examiner has failed to cite any support in Weitzel for this contention. Further, as evidenced by the Examiner's other contentions in the April 2, 2007 Office Action, neither Polaschegg, nor Derek, cure this above-mentioned deficiency of Weitzel. Accordingly, in addition to the reasons discussed above regarding independent claim 38, dependent claim 45, which indirectly depends from independent claim 38, is allowable over the cited references for at least this additional reason.

3. The Examiner Has Not Met His Burden In Establishing A Motivation To Combine The Teachings Of Weitzel, Polaschegg, and Derek

In the present case, the Examiner has failed to set forth sufficient evidence of a motivation to combine the teachings of Weitzel with the teachings of Polaschegg and Derek. One of ordinary skill in the art would have had no motivation to modify the blood treatment apparatus of Weitzel with the teachings of the blood treatment apparatus disclosed in Polaschegg and the oxygenation system disclosed in Derek as indicated by the Examiner. Indeed, in view of the way the blood treatment apparatus disclosed in Weitzel works, temperature is not detected at the inlet of the arterial line, nor would their have been any need for such temperature detection. Moreover, the has Examiner not provided explicit evidence in Weitzel that one of skill in the art would have been motivated to combine the teachings of Weitzel, with the teachings of Polaschegg or Derek. There is no suggestion that the temperature regulation disclosed in Weitzel is insufficient to control blood temperature as desired by the Weitzel inventors. Moreover, the Examiner's proposed modification of the apparatus disclosed in Weitzel with the teachings of Polaschegg is improper because such a modification actually teaches away from the claimed invention.

In particular, Polaschegg differs from Weitzel and the present invention in that blood temperature is controlled by warming or cooling the temperature of another fluid. In Fig. 1, dialysis fluid temperature is controlled and heat exchange occurs in dialyzer 202, while in Fig. 2, substitution fluid temperature is controlled and heat exchange occurs at the junction between line 402 and line 221. This results in indirect temperature control, which does not occur by using a temperature regulating device

downstream of all treatment elements. By only considering the position of sensor 206, the Examiner disregarded the true teaching of Polaschegg. One skilled in the art would read Polaschegg to teach indirect temperature control (i.e., controlling temperature of a different fluid using temperatures detected in the blood lines) and not temperature control of the claimed invention. Accordingly, the combination of Weitzel and Polaschegg actually teaches away from the temperature control recited in independent claim 26.

Furthermore, such a motivation to combine cannot be found in Polaschegg or Derek either. Nowhere in Polaschegg or Derek is the desirability of modifying the temperature regulation suggested.

The Examiner has failed to point to sufficient motivation in Weitzel, Polaschegg, or Derek to make the numerous modifications to the references to arrive at the claimed invention. There is simply no teaching in the cited references that suggests the desirability of making the exact combination or modification proposed by the Examiner. The mere fact that the references can be modified is not sufficient to support a *prima facie* case of obviousness. *See* M.P.E.P. § 2143.01(III). The only motivation to combine the references appears to originate from the Examiner's hindsight. Thus, the Examiner's prima facie case of obviousness is based on an impermissible hindsight analysis and the rejection is improper and should be withdrawn for at least this reason.

B. Conclusion

For the reasons given above, pending claims 26 and 28-50 are allowable, and Appellants respectfully request reversal of the outstanding rejections.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 11, 2007

By: _____

Aaron L. Parker
Reg. No. 50,785

VII. Claims Appendix

1-25. (Canceled)

26. (Previously Presented) An apparatus for control of an extracorporeal blood circuit connected to a blood purification machine, said extracorporeal blood circuit comprising an access branch, having one end connected to at least one blood treatment element inlet and another end connected to a patient, a return branch, having one end connected to an outlet of said at least one blood treatment element and another end connected to a patient; said apparatus comprising:

a sensor located in the access branch upstream of all blood treatment elements for measuring a first temperature of blood leaving a patient along the access branch upstream of said at least one blood treatment element;

a temperature regulating device for regulating said blood temperature in the extracorporeal blood circuit, said temperature regulating device comprising a line conveying a fluid, said line being coupled to a portion of the return branch downstream of all blood treatment elements to form a heat exchanger directly before blood is returned to the patient; and

a control unit connected to said temperature regulating device for controlling the blood temperature by controlling the temperature of the fluid conveyed in said line as a function of said first temperature and of a reference temperature.

27. (Canceled)

28. (Previously Presented) An apparatus according to claim 26, wherein said fluid in said line is capable of being heated to a fluid temperature lying within a specified range about 37°C.

29. (Previously Presented) An apparatus according to claim 26, wherein said regulating device has a seat for housing said portion of the return branch.

30. (Previously Presented) An apparatus according to claim 26, wherein said extracorporeal blood circuit is connected to a pump for conveying blood along the extracorporeal blood circuit, the apparatus comprising a sensor for detecting the operating state of said pump, the control unit maintaining the fluid temperature of said fluid equal to said reference temperature when said pump is not in operation.

31. (Previously Presented) An apparatus according to claim 26, wherein said return branch comprises an expansion chamber, said portion of the return branch being located downstream of the expansion chamber.

32. (Previously Presented) An apparatus according to claim 26, wherein said at least one blood treatment element is formed by a hemodialysis filter comprising a blood compartment and a dialysate compartment, said dialysate compartment having a dialysate flowing therein.

33. (Previously Presented) An apparatus according to claim 26, wherein said at least one blood treatment element comprises a hemodialysis filter comprising a blood compartment and a dialysate compartment, said dialysate compartment having a dialysate flowing therein, and an expansion chamber, said expansion chamber receiving a replacement fluid.

34. (Previously Presented) An apparatus according to claim 26, wherein said at least one blood treatment element is formed by a hemofiltration filter.

35. (Previously Presented) An apparatus according to claim 26, wherein said at least one blood treatment element comprises a hemofiltration filter and an expansion chamber, said expansion chamber receiving a replacement fluid.

36. (Previously Presented) An apparatus according to claim 26, wherein said control unit controls the temperature of the fluid in said line, to regulate the blood temperature in the extracorporeal blood circuit, as a function of the first temperature and of the reference temperature at predetermined intervals of time.

37. (Previously Presented) An apparatus according to claim 26 or 36, wherein said control unit controls the temperature of the fluid in said line, to regulate the blood temperature in the extracorporeal blood circuit, as a function of a difference between the first temperature and the reference temperature.

38. (Previously Presented) A control method for an extracorporeal blood circuit for the circulation of blood in a blood purification machine, the extracorporeal blood circuit comprising an access branch and a return branch, said access branch and return branch being connected to at least one blood treatment element, the control method comprising the steps of:

connecting the access branch to a patient and to an inlet of said blood treatment element;

connecting the return branch to the patient and to an outlet of said blood treatment element;

measuring a first temperature of the blood in correspondence of said access branch upstream of all blood treatment elements; and

regulating a blood temperature in the extracorporeal blood circuit as a function of the first temperature and of a reference temperature, the blood temperature in the extracorporeal blood circuit being regulated along a portion of the return branch and downstream of all blood treatment elements, directly before blood is returned to the patient.

39. (Previously Presented) A control method according to claim 38, wherein the steps of measuring a first temperature of blood leaving a patient along the access branch and of regulating the blood temperature in the extracorporeal blood circuit as a function of the first temperature and of a reference temperature are repeated at intervals of time.

40. (Previously Presented) A method according to claim 38, wherein a temperature difference between the first temperature and the reference temperature is calculated, said blood temperature in the extracorporeal blood circuit being regulated as a function of said temperature difference.

41. (Previously Presented) A method according to claim 40, further comprising a step of regulating a heat exchange of a heat exchanger, said heat exchanger comprising said portion of the return branch and a temperature regulating device connected to said portion of the return branch.

42. (Previously Presented) A method according to claim 40, wherein heat is withdrawn from blood along said portion of the return branch when said temperature difference is positive.

43. (Previously Presented) A method according to claim 40, wherein heat is supplied to the blood along said portion of the return branch when said temperature difference is negative.

44. (Previously Presented) A method according to claim 38, wherein a fluid is conveyed along said temperature regulating device, said fluid having a fluid temperature that varies within a specified range about 37° C.

45. (Previously Presented) A method according to claim 44, wherein blood is conveyed along the extracorporeal blood circuit by means of a pump, a state of operation of the pump being detected, the fluid temperature being regulated as a function of the first temperature and of the reference temperature, and the fluid temperature being kept equal to the reference temperature when the pump is not in operation.

46. (Previously Presented) A method according to claim 38, wherein the reference temperature is varied according to a specified profile.

47. (Previously Presented) A method according to claim 38, wherein said extracorporeal blood circuit is used for a hemodialysis treatment; said at least one blood treatment element being formed by a hemodialysis filter through which blood and a dialysate flow in a counterflow mode.

48. (Previously Presented) A method according claim 38, wherein said extracorporeal blood circuit is used for a hemodiafiltration treatment; said at least one blood treatment element comprising a hemodialysis filter through which blood and a dialysate flow in a counterflow mode, said at least one blood treatment element further comprising an expansion chamber supplied with a replacement fluid.

49. (Previously Presented) A method according to claim 38, wherein said extracorporeal blood circuit is used for a pure hemofiltration treatment, said at least one blood treatment element comprising a hemofiltration filter through which blood flows.

50. (Previously Presented) A method according to claim 38, wherein said extracorporeal blood circuit is used for a hemofiltration treatment, said at least one blood treatment element comprising a hemofiltration filter through which blood flows, said at least one blood treatment element further comprising an expansion chamber supplied with a replacement fluid.

VIII. Evidence Appendix

No evidence is being relied upon herein by the Appellant.

IX. Related Proceedings Appendix

No related proceeding decisions are relied upon herein by Appellants.